UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

HERMAN MARKS,

Plaintiff,

CASE NUMBER: 08-cv-3552-SHS

-against-

JURY TRIAL REQUESTED

JOHNSON & JOHNSON, ORTHO-MCNEIL PHARMACEUTICAL, INC., and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC

Defendants.

----------X

FED. R. CIV. P. 26(F) REPORT

The pretrial conference in the above-captioned action is scheduled for Friday, June 13, 2008 at 12:00 p.m. before United States District Court Judge Sidney H. Stein in Courtroom 23A, 500 Pearl Street, New York, NY 10007.

Plaintiff Herman Marks and Defendants Johnson & Johnson; Ortho-McNeil Pharmaceutical, Inc.; and Johnson & Johnson Pharmaceutical Research and Development LLC conducted their meeting required by Fed. R. Civ. P. 26(f) on May 22, 2008 at 1 p.m. via telephone.

Plaintiff was represented at the Rule 26(f) meeting by:

Kevin M. Fitzgerald, Esq.
Lewis Saul & Associates, P.C.
183 Middle Street, Suite 200
Portland, ME 04101
Phone: (207) 874-7407

All three defendants were represented at the Rule 26(f) meeting by:

John Winter, Esq.
Patterson, Belknap, Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2222

The parties' respective positions regarding a proposed discovery plan are set forth below.

1. DESCRIPTION OF CASE AND STATUS OF LEVAQUIN LITIGATION

Plaintiff's Statement

Defendants developed, manufacture and sell the antibiotic Levaquin, a fluoroquinolone antibiotic generally indicated for severe infections caused by specific bacteria. The first fluoroquinolones entered the U.S. market in the mid 1980s. After ten years on the market, the FDA had received 52 reports of tendon injury, including tendon rupture, potentially related to the ingestion of a total of five different fluoroquinolones. Accordingly, in 1996, the FDA required that all fluoroquinolones carry a warning regarding the possibility of tendon rupture. With only 52 cases of tendon injury reported among 5 fluoroquinolones over a ten year period (and some cases involving reports from other countries), this side effect was considered rare to those physicians who knew of it.

After Defendants launched Levaquin in 1997, and after Levaquin sales began to rapidly increase through the years, tendonitis and tendon ruptures were increasingly reported to the FDA with over 1,000 cases of tendon injury associated with Levaquin use being reported between 1999-2005. Plaintiffs therefore allege that while tendon injury may be rare with earlier fluoroquinolones, it is certainly not a rare occurrence with Levaquin.

The most common Levaquin-induced tendon injury affects the Achilles tendon, the strongest and most weight-bearing of all tendons. One study suggests that approximately half of

the Achilles injuries are bilateral and rupture occurs in 75% of all cases. Although few studies have evaluated the mechanism of how Levaquin damages tendons, the general theory is that Levaquin causes a programmable cell death of the tendon cells (tenocytes), called apoptosis, that leads to rupture once the cell death has accelerated. Achilles tendon rupture is a serious condition, often requiring surgical repair. After repair, the tendon must be immobilized for up to six months, forcing victims of bilateral rupture to be wheelchair bound.

Plaintiff alleges that Levaquin is associated with more tendon injury than any other fluoroquinolone. As such, Levaquin has a design defect in that it is more dangerous than other similar fluoroquinolones on the market today. Additionally, Defendants have failed to warn of the risk of Levaquin tendon injury and consequently, physicians and patients are ill-informed and unable to adequately perform a risk/benefit analysis when deciding whether to prescribe or ingest Levaquin. Plaintiff further asserts that a black box warning is appropriate when an adverse event as serious and disabling as Achilles tendon rupture is occurring in astonishing high numbers. Today, Levaquin is the number one prescribed antibiotic in the country.

As a direct result of ingesting Levaquin, Plaintiff Marks suffered bilateral Achilles tendon tears causing him substantial injury and permanent disability.

There are currently 21 actions, including this case, filed in 11 different District Courts involving 30 plaintiffs claiming tendon-related injuries due to their use of Levaquin. A majority of the cases, including the actions styled *Voss et al. v. Johnson & Johnson et al.,* Case No. 06-cv-03728-JRT-AJB (D. Minn.); *Griner v. Johnson & Johnson et al.,* Case No. 07-cv-01584-JRT-AJB (D. Minn.); *Beardsley v. Johnson & Johnson et al.,* Case No. 07-cv-01661-JRT-AJB (D. Minn.); *Kirkes et al. v. Johnson & Johnson et al.,* Case No. 07-cv-01862-JRT-AJB (D. Minn.); *Parr v. Johnson & Johnson et al.,* Case No. 07-cv-02999-JRT-AJB (D. Minn.); *Christensen et*

al. v. Johnson & Johnson et al., Case No. 07-cv-03960-JRT-AJB (D. Minn.); *Shaffer v. Johnson & Johnson et al.,* Case No. 07-cv-4617-JRT-AJB (D. Minn.); and *Cottle v. Johnson & Johnson et al.,* Case No. 08-cv-00277-JRT-AJB (D. Minn.) (hereafter collectively as "Minnesota Cases"), have been filed in Minnesota by Plaintiff's counsel hereunder and are consolidated before Judge John R. Tunheim. Of the Levaquin actions involving tendon injuries currently pending in federal court, the Minnesota Cases were the first filed.

The Minnesota Cases have been placed into two trial groups with corresponding scheduling orders. Discovery has been ongoing in the Minnesota Cases for over a year. The parties have served and answered, in part, initial disclosures and case-specific and common issue interrogatories and requests for production of documents. Plaintiffs have produced medical and other records to Defendants. Defendants have already produced over one million pages of documents in paper or electronic format to Plaintiffs. Additionally, Plaintiffs have begun to take depositions of key corporate witnesses. Although significant discovery has been exchanged, a substantial amount of discovery remains to be conducted including, but not limited to, additional document production; Defendants' production of certain databases related to Levaquin; depositions of fact witnesses, including treating physicians; and all expert witness discovery. The first trial date in the Minnesota Cases is scheduled for January 1, 2010.

Defendant's Statement

Defendants Johnson & Johnson, Ortho McNeil Pharmaceutical, Inc., and Johnson & Johnson Pharmaceutical Research and Development, LLC dispute that plaintiff can prove to a reasonable degree of medical certainty that Levaquin caused his alleged injuries.

Further, defendants assert that plaintiff's claims relating to the use of Levaquin fall under the auspices of the Food, Drug, and Cosmetic Act and regulations promulgated by the Food and

Drug Administration ("FDA"), and are therefore preempted by Federal Law. *See* 21 U.S.C. §§ 301 to 399, Fed. Reg. 3922 (January 24, 2006).

Moreover, Levaquin was approved by FDA and other government authorities. Defendants acted at all times in compliance with FDA's rules and regulations and of other governmental authorities. FDA has determined that Levaquin is reasonably safe for its intended use as an antibiotic and has acknowledged certain risks with the drug's use. Defendants properly warned plaintiff's prescribing physician of the known risks of using Levaquin.

In addition, Levaquin was in conformity with the state of the art scientific knowledge at the relevant times involved.

Finally, plaintiff cannot show that Levaquin is defective or unreasonably dangerous.

2. PLEADINGS

To date, all process has been served and pleadings filed. Both parties have timely demanded a trial by jury and it is available under the law. The parties agree that any motion to amend the pleadings or add new parties will be filed by October 1, 2008.

3. PROPOSED DISCOVERY PLAN

a. Date by which Rule 26(a)(1) disclosures to be made.

The parties agree that Rule 26(a)(1) disclosures will be completed and served by August 1, 2008.

b. Whether discovery should be conducted in phases, or limited to or focused upon, particular issues.

The parties agree that discovery is not to be conducted in phases other than as further outlined below.

c. Date by which Rule 26(a)(2) disclosures to be made.

Plaintiff's Proposal

Plaintiff proposes that Plaintiff's production of expert witnesses and reports under Rule 26(a)(2)(A) and (B) will be completed and served by July 6, 2009; Defendants' production of expert witnesses and reports under Rule 26(a)(2)(A) and (B) will be completed and served by August 24, 2009; and Plaintiff's production of rebuttal expert witnesses and reports under Rule 26(a)(2)(A) and (B) will be completed and served by October 12, 2009.

Defendants' Proposal

Defendants propose that plaintiff identify and submit his expert witnesses and reports pursuant to Rules 26(a)(2)(A) and (B) no later than May 8, 2009; defendants will identify and submit their 26(a)(2) reports by June 26, 2009; and all rebuttal 26(a)(2) reports will be served no later than August 14, 2009.

d. The number of interrogatories each party shall be permitted to serve.

The parties agree to adopt the numbers regarding interrogatories as set forth in the Amended Pretrial Scheduling Orders in the Minnesota Cases. Accordingly, no more than 25 case-specific interrogatories, counted pursuant to Fed. R. Civ. P. 33(a), shall be served by either side in this case. Each side may serve 50 interrogatories regarding matters common to Plaintiff Marks and plaintiffs in the Minnesota Cases.

e. The number of depositions (excluding expert depositions) each party shall be permitted to take.

The parties agree to adopt the numbers regarding depositions (excluding expert witnesses) as set forth in Amended Pretrial Scheduling Orders in the Minnesota Cases. Accordingly, no more than 10 case-specific depositions, excluding expert witness depositions,

shall be taken by either side in this case. Each side may take 30 depositions regarding matters common to Plaintiff Marks and plaintiffs in the Minnesota Cases.

f. The number of expert depositions each party shall be permitted to take.

The parties agree to adopt the numbers regarding expert depositions as set forth in Amended Pretrial Scheduling Orders in the Minnesota Cases. Accordingly, unless otherwise agreed to or permitted by court order, each side shall take no more than 3 expert depositions with respect to the Plaintiff. Each side may take 6 expert depositions regarding matters common to Plaintiff Marks and plaintiffs in the Minnesota Cases.

g. Date by which fact discovery shall be complete.

Plaintiff's Proposal

Plaintiff proposes that all fact discovery shall be completed by June 1, 2009.

Defendants' Proposal

Defendants propose that all fact discovery shall be completed by April 3, 2009.

h. Date by which expert discovery shall be complete.

Plaintiff's Proposal

Plaintiff proposes that depositions of Plaintiff's experts shall be completed by November 20, 2009 and depositions of Defendants' experts by January 1, 2010.

Defendants' Proposal

Defendants propose that depositions of plaintiff's experts shall be completed by September 18, 2009 and depositions of defendants' experts be completed by October 16, 2009.

i. Deadline for Non-dispositive motions.

Plaintiff's Proposal

Plaintiff proposes that all non-dispositive motions be filed by January 1, 2010.

Defendants' Proposal

Defendants propose that all non-dispositive motions be filed by October 18, 2009.

4. DISPOSITIVE MOTIONS AND TRIAL

a. Deadline for Dispositive motions.

Plaintiff's Proposal

Plaintiff proposes that all dispositive motions be filed by January 15, 2010.

Defendants' Proposal

Defendants propose that all dispositive motions be filed by November 20, 2009.

b. Date by which case will be ready for trial.

Plaintiff's Proposal

Plaintiff proposes that this case shall be ready for trial on April 12, 2010.

Defendants' Proposal

Defendants propose that this case shall be ready for trial on February 8, 2010.

c. Estimated trial length

The parties agree that the estimated trial time, including jury selection and instructions, will run three weeks.

d. Number of expert witnesses to be called at trial

Counsel for the parties anticipate that each party will call 7-10 expert witnesses at trial.

Date: May 30, 2008

Respectfully submitted,

/s/ Lewis J. Saul

Lewis J. Saul, Esq.
LEWIS SAUL & ASSOCIATES, P.C.
29 Howard Street, #3
New York, NY 10013
Phone: (212) 226-3413
Facsimile: (212) 226-3774
lsaul@lewissaul.com;
kfitzgerald@lewissaul.com

Attorneys for Plaintiff

Dated: May 30, 2008

Respectfully submitted,

/s/ John Winter

John Winter, Esq.
Patterson, Belknap, Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2222
Facsimile: (212) 336-2369
Jwinter@PBWT.com

Attorneys for Defendants

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

HERMAN MARKS,

Plaintiff,

CASE NUMBER: 08-cv-3552-SHS

-against-

JURY TRIAL REQUESTED

JOHNSON & JOHNSON, ORTHO-MCNEIL PHARMACEUTICAL, INC., and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC

Defendants.

----------X

CERTIFICATE OF SERVICE

I hereby certify that on May 30, 2008, I electronically filed the foregoing Rule 26(f) Report using the Court's ECF/CM System, which will send electronic notice of the foregoing filing to all registered users admitted in this case, including:

Lewis Saul	lsaul@lewissaul.com; kfitzgerald@lewissaul.com
John Winter	Jwinter@PBWT.com

Date: May 30, 2008

Respectfully submitted,

/s/ Lewis J. Saul

Lewis J. Saul, Esq.
LEWIS SAUL & ASSOCIATES, P.C.
29 Howard Street, #3
New York, NY 10013
Phone: (212) 226-3413
Facsimile: (212) 226-3774
lsaul@lewissaul.com

Attorneys for Plaintiff